UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,526	07/11/2003	Frits Jacobus Fallaux	2578-3833. 9US	5055

24247 7590 08/29/2005

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,526	FALLAUX ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-11,16 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-11,16 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/793,170.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20041209, 20050805*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.07

DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1633.

The request for reconsideration filed 8/5/05 of the final rejection mailed 4/6/05 is acknowledged. Applicant had provided terminal disclaimers in response to the Office action of 12/1/04 that had not been considered. Consequently, the final rejection mailed 4/6/05 is withdrawn. In addition, new rejections and provisional rejections are set forth below.

It appears from the records available to the Examiner that assignment papers have not been filed in the instant application. The terminal disclaimers filed 2/28/05 and 4/1/05 indicate that the instant application is wholly owned by Crucell Holland B.V. Applicant is urged to file the appropriate assignment papers, or to contact Assignment Branch if such papers have been filed to determine if they have been received by the PTO.

Information Disclosure Statement

The information disclosure statement filed 8/5/05 includes opposition documents filed in the EPO concerning an EP patent issued from the PCT related to the instant application. It is not entirely clear what the claims in the EP patent are. The arguments presented in these opposition documents appear to ignore claim language requiring that the cell be an adenoviral packaging cell (present in the preamble of the instant claims, and apparently present in the EP patent as

well). This limitation has weight, it limits the cell to one in which a replication-defective adenovirus can replicate and be packaged or produced. Adenoviral replication and virion production requires not only viral gene products but also host cell products in a complex, temporally regulated process. Adenoviral replication is known to be host specific. The primary references relied upon in the opposition documents relate to the use of human Ad5 E1A and E1B 19k coding sequences to immortalize or transform rodent cells. No evidence is provided in the opposition documents that such cells would support replication or virion formation of hAd5 or any other adenovirus, and certainly no evidence that one of skill in the art would have considered such cells to be adenoviral packaging cells. Consequently, the opposition documents and the prior art upon which they rely are not deemed to be relevant to the patentability of the instantly claimed invention.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

The declaration filed 7/11/03, which is a copy of the declaration filed in application 09/506,548, does not identify the EP 95201728.3 application filed 6/26/95.

Specification

The disclosure is objected to because of the following informalities. In paragraph 0001, line 4, as amended 2/28/05, the '548 application was filed 2/16/00, not 2/17/00 as recited.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1, 3-7, 9-11, 16, and 21-24 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The subject matter of the instant claims embraces subject matter disclosed in the claims of one or more of the commonly assigned patents and applications listed below, i.e. the claims of these patents and applications anticipate the instant claims. These commonly assigned patents and applications either share no common inventor with the instant application or share only Inventor Bout with the instant application. The commonly assigned patents and applications and their relevant claims are: claim 3 of commonly assigned U.S. Patent No. 6,395,519; claim 11 of commonly assigned U.S. Patent No. 6,447,768; claims 1-5 of commonly assigned U.S. Patent No. 6,670,188; claims 15, 19 and 26 of commonly assigned U.S. Patent No. 6,855,544; claims 1-13 of commonly assigned U.S. Patent No. 6,869,794; claims 18-22 of commonly assigned Application No. 10/002,750; claim 33 of commonly assigned Application No. 10/432,105; claims 98 and 107 of commonly assigned Application No. 10/494,140; claims 51, 67, and 82 of

commonly assigned Application No. 10/497,832; claims 27 and 54 of commonly assigned Application No. 10/512,589; claim 5 of commonly assigned Application No. 10/644,256; and claims 8, 35, and 58 of commonly assigned Application No. 11/039,767.

The subject matter of the instant claims embraces subject matter disclosed in the claims of one or more of the following patents or applications that share some, but not all, inventors in common with the instant application, i.e. the claims of these patents and applications anticipate the instant claims. These patents or applications do not appear to be commonly assigned with the instant application. These patents or applications and their relevant claims are: claims 43 and 44 of U.S. Patent No. 6,340,595 (Galapagos Genomics N.V.); claims 7, 32, and 35 of U.S. Patent No. 6,413,776 (Galapagos Genomics N.V.); claim 11 of U.S. Patent No. 6,447,768; claims 2, 4, and 6 of U.S. Patent No 6,878,549 (Introgene B.V.); claims 67 and 95 of copending Application No. 10/036,949 (inventors); and claim 11 of copending Application No. 11/083,590.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 9 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,033,908. This is a double patenting rejection.

Claim 9 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 33 of copending Application No. 10/125,751. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7, 9-11, 16, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: claims 43 and 44 of U.S. Patent No. 6,340,595; claim 3 of U.S. Patent No. 6,395,519; and claims 7, 32, and 35 of U.S. Patent No. 6,413,776.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly adenoviral packaging cells embrace: the packaging cells used in the methods of claims 43 and 44 of the '595 patent; the cell of claim 3 of the '519 patent; the cells used in the method of claims 7, 32, and 35 of the '776 patent;

Claims 1, 3-7, 9, 16, 21 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,447,768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed cells embrace the cell of the system of claim 11, which is presumed to depend from claim 7, not claim 3 (PER.C6 transfected with an adenoviral vector not having overlapping adenoviral sequences with PER.C6).

Claims 1, 3-7, 9-11, 16, 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,670,188. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '188 patent are directed generally to a method for making stocks of recombinant adenovirus free of replication competent adenovirus, and packaging cells used for that method. The claims do not explicitly recite that the packaging cell has E1A and E1B complementing sequences in the absence of pIX coding sequences or additionally E2A complementing sequences. However, when read in light of the specification of the patent (which is essentially the same as the instant specification), the claims implicitly embrace the various embodiments of packaging cells instantly claimed that are described in the supporting disclosure of the patent specification.

Claims 1, 3-7, 9, 16, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,869,794; claims 2, 4, and 6 of U.S. Patent No 6,878,549; and claims 15, 19 and 26 of U.S.

Patent No. 6,855,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented cells of '794 are embraced by the instant claims and the methods of claims of the '549 and '544 patents require PER.C6 (a.k.a. ECACC 96022940), which is embraced by the instant claims.

The following are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claims 1, 3-7, 9, 16 and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: claims 18-22 of copending Application No. 10/002,750; claims 67 and 95 of copending Application No. 10/036,949; claims 70-100 of copending Application No. 10/136,139; claim 33 of copending Application No. 10/432,105; claims 98 and 107 of copending Application No. 10/494,140; claims 51, 67, and 82 of copending Application No. 10/497,832; claims 27 and 54 of copending Application No. 10/512,589; claim 5 of copending Application No. 10/644,256; claim 8 of copending Application No. 10/850,140; claims 8, 35, and 58 of copending Application No. 11/039,767; and claim 11 of copending Application No. 11/083,590. Although the conflicting claims are not identical, they are not patentably distinct from each other because: the methods of the '750 claims use a cell derived from PER.C6, which is embraced by the instant claims; the methods of the '949 claims use PER.C6; the packaging system of the '139 claims are directed to a combination that comprises the instantly claimed cell lines; the process of the '105 claim uses PER.C6; the methods of the '140; claims use ECACC 96022940 (PER.C6); the methods of the '832 claims

use PER.C6; the methods of the '589 claims use PER.C6; the cell of the '256 claim is embraced by the instant claims; the method of the '140 claim uses PER.C6; the methods of '767 claims 8 and 58 use PER.C6 and the cell of '767 claim 35 is embraced by the instant claims; and the method of the '590 claim uses PER.C6.

Claims 1, 3-7, 9-11, 21, 22 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 30-33, 35-38, and 40-50 of copending Application No. 10/038,271 and claims 1-31 of copending Application No. 11/134,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods claimed in the '271 and '674 applications explicitly use the instantly claimed cells and the packaging systems or the '674 claims comprise cells embraced by the instant claims.

It is noted that a terminal disclaimer cannot be filed over US 6,340,595 and 6,413,776, which share Inventor Bout with the instant application, since these applications (assigned to Galapagos Genomics N.V.) are not commonly assigned with the instant application, although it appears that their corresponding applications, when filed, had been commonly assigned with the parent applications to the instant application. Also, US 6,878,549 appears to be currently assigned to Introgene B.V., which was the former assignee of some parent applications to the instant application. A terminal disclaimer cannot be filed over these latter patents unless they are now assigned to Crucell Holland (if so, assignment papers should be filed with the PTO). Applications 10/036,949 and 11/083,590, which shares only Inventor Bout with the instant

application, appear to be assigned to their inventors, and a terminal disclaimer cannot be filed unless the applications are assigned to Crucell Holland (if so, assignment papers should be filed with the PTO). Applications 10/850,140 and 11/134,675 appear to be currently assigned to the instant inventors, and a terminal disclaimer cannot be filed unless the application is assigned to Crucell Holland (if so, assignment papers should be filed with the PTO).

It is noted that papers filed in applications 10/038,271 and 10/136,139 indicate that these applications are currently owned by Crucell Holland. However, no assignment papers are listed for these applications in records available to the Examiner.

The terminal disclaimers filed on 2/28/05 and 4/1/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of U.S. Patents 5,994,128; 6,033,908; 6,265,212; 6,306,652; 6,692,966 and of patents granted on U.S. Application Nos. 10/125,751; and 10/219,414 have been reviewed and accepted. The terminal disclaimers have been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER